

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83965

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

Page(s) 1

Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

re - ANDA other
than 83-965

ADA 83-943

Canall Co.
Attention: Mr. Eugene Schwall
11401 East 7 Mile Road
Detroit, MI 48234

MAR 05 1974

Gentlemen:

Reference is made to your abbreviated new drug application dated September 11, 1973, submitted pursuant to Section 305(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mgs.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. Copies of printed labeling, as per the submitted drafts.
2. Additional information regarding the supplier, including a manufacturer's certificate of analysis.
3. Indication of the exact analytical procedures to be performed on your behalf by:
4. The analytical procedures to be performed on the drug dosage form. We note that a specifications sheet was submitted—but for diethylpropion HCl.
5. It is also required that you submit adequate data to assure the biologic availability of the drug in the formulation marketed or proposed for marketing. At this time, it is the policy of the Administration to request a proposed protocol from you. This protocol should outline methods you plan to use to determine biologic availability. It is recommended that you not initiate any actual investigation until we have commented upon the submitted protocol.

We call to your attention the following evaluation of the Bureau of Drugs, Office of Compliance, in regard to your Labs' compliance with GMP regulations:

Canall Co.
NDA 83-963

-2-

We have evaluated the operations of the two above-referenced firms as they relate to compliance with Current Good Manufacturing Practice Regulations (21 CFR, Part 133). On the basis of this evaluation, we cannot approve the subject ANDAs as the firms are not operating in conformance with Part 133 to assure that products meet the requirements of the Federal Food, Drug, and Cosmetic Act as to safety, and have the identity and strength, and meet the quality and purity standards which they purport to possess.

Inspection of _____, -/27-10/17/73, revealed significant deviations from CGMP Regulations as well as

Inspection of _____ on 12/3/73 revealed significant deviations from CGMP Regulations in the area of laboratory controls.

To expedite the handling of this application, it is also request that you submit samples of (a) the active ingredient and (b) finished tablets.

Please submit twelve copies of printed labeling; and let us have your response promptly.

Sincerely yours,

IS/ 3/4/74
MARVIN L. LIRA, M.D.
Director
General Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
IS/ 12/6/74

NDA 23-965

SEP 24 1973

Cumall Company
Attention: Mr. Eugene Schmall
11401 East 7 Mile Road
Detroit, Michigan 48234

Gentlemen:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 305(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF APPLICATION: September 11, 1973

DATE OF RECEIPT: September 5, 1973

We will correspond with you further after we have had the opportunity to review the application.

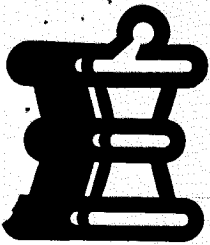
We would also like to call to your attention the Federal Register of March 15, 1973 (38 F.R. 7001) regulations establishing procedures for preparation of Environmental Impact Statements (Part 6 - Environmental Impact Considerations). Section 6.1(e) of these regulations requires that the applicant include an environmental impact analysis report as part of any new-drug application. Failure to submit an environmental impact analysis report is grounds for refusing to file or to approve an application (21 CFR 130.5(a)(8) or 130.12(a)(7)).

Please identify any communications concerning this application with the NDA number shown above.

Sincerely yours,

/S/
Marvin Seife, M.D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

CH



Ken W. H.
RESUBMISSION

CAMALL COMPANY

NDA ORIG AMENDMENT

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1948

PERSONALLY SUBMITTED BY

Fred Henderson
Rec'd by BDD
8-5-74

ORIG

July 24, 1974

Department of Health, Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Md. 20852

Attention: Dr. M. Seife, M.D.

Re: NDA 83-965 for the drug Hydrochlorothiazide Tablets
50 mg., and your letter dated March 5, 1974

Dear Dr. Seife,

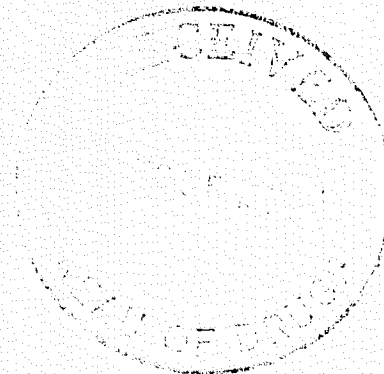
Camall Company is submitting this protocol for
the bioavailability study for Hydrochlorothiazide
Tablets 50 mg. NDA 83-965, according to your letter of
March 5, 1974.

Sincerely,

Eugene M. Schmall

Eugene M. Schmall
President, Camall Co.

EMS:aw



NDA 83-965

AF _____

Camall Co.
Attention: Mr. Eugene Schwall
11401 East 7 Mile Road
Detroit, MI 48234

FEB 13 1975

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

We acknowledge receipt of your communication dated January 9, 1975.

Reference is also made to our letters of March 5, 1974 and October 7, 1974.

We have completed the review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. The labeling requested in our letter of March 5, 1974.
2. The manufacturing information then requested.
3. Adequate data to assure the bioavailability of your formulation -- in accord with our comments of October 7, 1974.

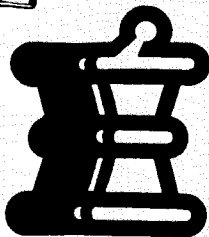
Please let us have your response promptly.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

2/12/75



ORIG NEW CORRES

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1900 620

January 9, 1975

Dept. HEW
Public Health Service
Food and Drug Adm.
Rockville, Md. 20852

Gentlemen,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

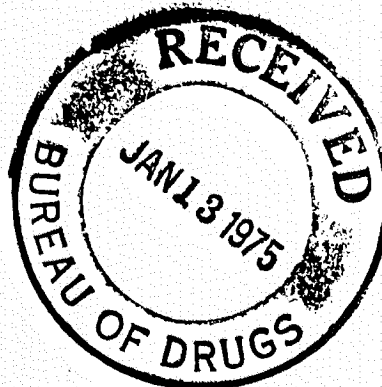
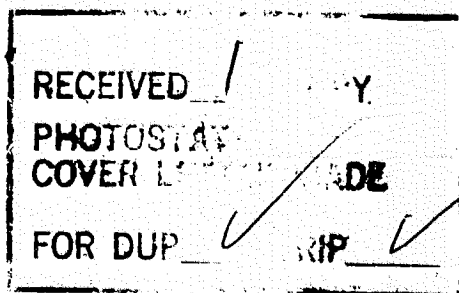
Re: Compendium Identification tests for Silicon Dioxide

Enclosed find the Analytical Report on Aerosil.

Sincerely,

Eugene M. Schmall
CAMALL COMPANY

ES/jg



NDA 89-965

AP 13-313

OCT 07 1974

Conall Company

Attention: Mr. Eugene M. Schmall

11401 East 7 Mile Road

Detroit, MI 48234

Gentlemen:

Reference is made to the protocol you submitted for bioavailability studies for Hydrochlorothiazide Tablets, 50 mg.

The protocol has been reviewed by our Division of Clinical Research and they have the following comments:

1. Each subject will be given a general physical examination including a medical history.
2. Each drug should be assayed for potency. In addition, dissolution studies should be conducted.
3. Tea and carbonated beverages are to be prohibited during the test days.
4. The amount of water intake prior to dosage for both test days should be the same.
5. The -1 to 0, 4-6, and 6-8 hour urine collection times which were omitted should be included.
6. The lot number's and the size of the production test batch should be remitted.
7. Each subject should be free of significant gastrointestinal, renal, and hepatic disease.
8. Each subject is to be informed that he is entirely free to withdraw from participation in the study at any time. Provision should be made for more than 20 volunteers to anticipate subject withdrawal.

RECOMMENDATION:

The protocol is acceptable provided the above suggestions are incorporated into the study.

Handwritten signature

/S/

Marvin Seire, M.D.

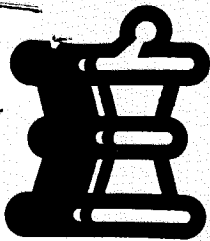
Director

Generic Drug Staff

Office of Scientific Evaluation

Bureau of Drugs

MEMO RECORD	· AVOID ERRORS PUT IT IN WRITING	DATE
FROM:		OFFICE
TO:		DIVISION
SUBJECT:		
SUMMARY		
<p>83-965</p> <p>Hydrochlorothiazide</p> <p>Tab. 50mg.</p> <p>Camall Co.</p>		
SIGNATURE		DOCUMENT NUMBER



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1948

March 31, 1975

ORIG NEW CORRES

ORIG

Food and Drug Adm.
Office of Scientific Evaluation
Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20852
Marvin Seife, M.D.-Director

Dear Dr. Seife,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

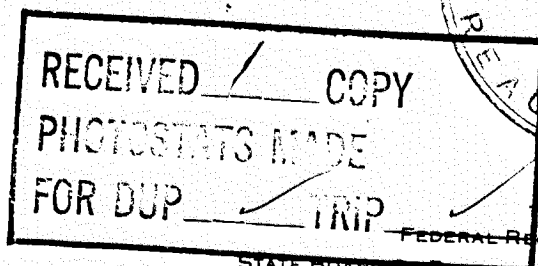
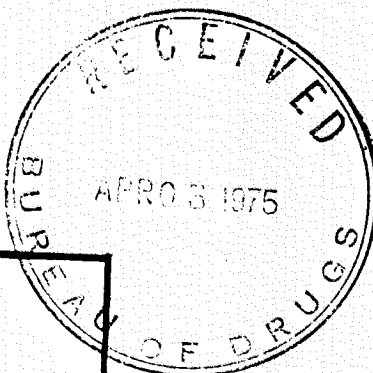
Re: Addition of final reconciliation sheet.

See attached sheet.

Sincerely,

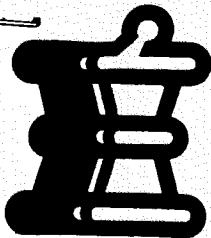
Eugene M. Schmall
CAMALL COMPANY

EMS/jg



FEDERAL REGISTRATION No. 18-10703

STATE BOARD OF PHARMACY No. 0031 AND BNDD No. PC0010152



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1989 0620

ORIG NEW CORRES'

February 24, 1975

Food and Drug Adm.
Office of Scientific Evaluation
Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20852
Marvin Seife, M.D.-Director

Dear Dr. Seife,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50mg.

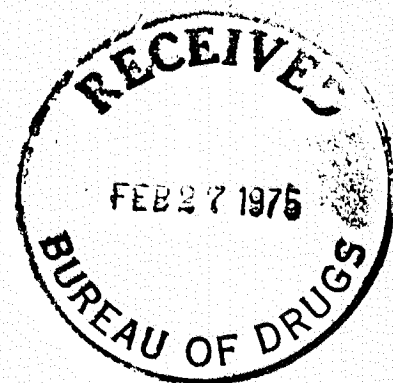
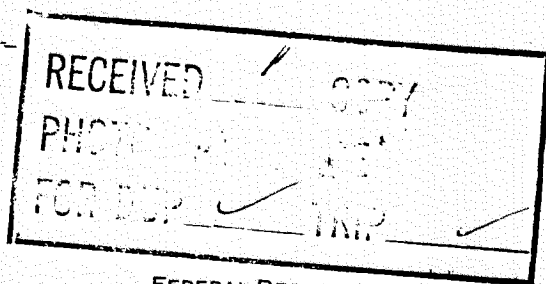
Re: Supplier's Drug Master File Number

See attached sheet.

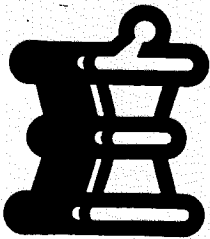
Sincerely,

Eugene M. Schmall
CAMALL COMPANY

Enc. Letter from Gyma Labs. stating DMF number.
EMS/jmg



FEDERAL REGISTRATION NO. 18-10703
STATE BOARD OF PHARMACY NO. 0031 AND BNDD NO. PC0010152



ORIG NEW CORRES

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1948-0620

February 18, 1975

Food and Drug Adm.
Office of Scientific Evaluation
Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20852
Marvin Seife, M.D.-Director

Dear Dr. Seife,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

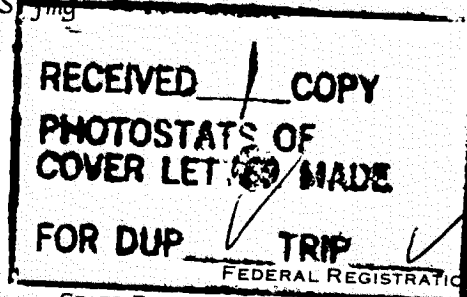
Re: Revision of bottling and labeling sheet.

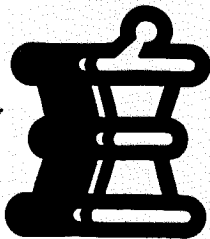
See attached sheets.

Sincerely,

Eugene M. Schmall
CAMALL COMPANY

Enc. Bottling sheet-Blue color Labeling sheet-Blue color
EMS/jmg





CAMALL COMPANY

NDA ORIG AMENDMENT

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1111

February 6, 1975

Dept. HEW
Food and Drug Adm.
5600 Fishers Lane
Rockville, Md. 20852
Marvin Seife, M.D.

Dear Dr. Seife,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

F D & C Yellow

Spec Sheet revision

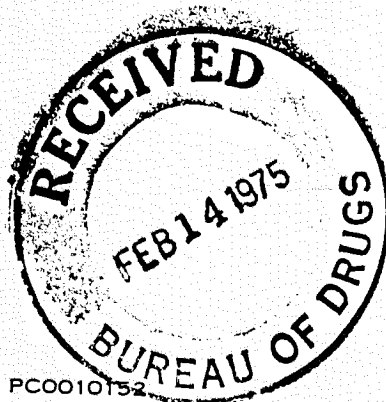
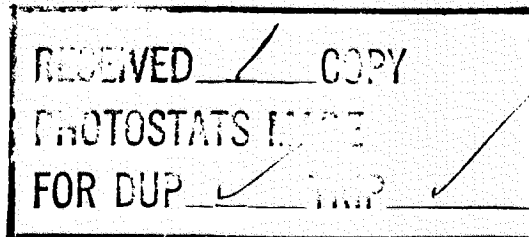
See attached sheet.

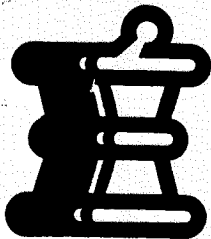
Sincerely,

Eugene M. Schmall

CAMALL COMPANY

EMS/jmg





NDA ORIG AMENDMENT

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 37200000620

January 9, 1975

FPL

Food and Drug Adm.
1560 E. Jefferson
Detroit, Michigan 48226

RECEIVED 1 COPY
PHOTOSTATS OF
COVER LETTER MADE
FOR DUP 1 TRIP 1

Gentlemen,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

Re: labeling

Enclosed find six (6) labels for Hydrochlorothiazide Tablets
50 mg.

Enclosed find six (6) labels for Hydrochlorothiazide Tablets 50 mg.

1.

2.

3.

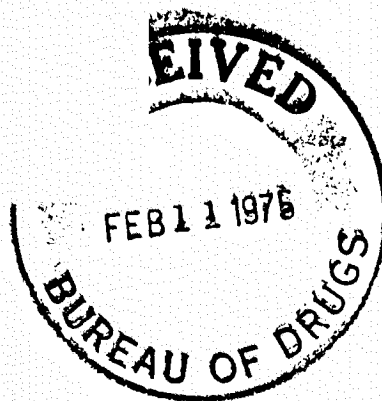
4.

5.

Co., Inc

Sincerely,

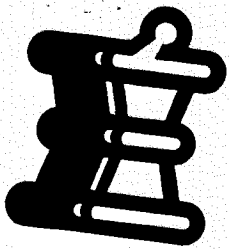
Eugene M. Schmall
CAMALL COMPANY



ES/jg

FEDERAL REGISTRATION No. 18-10703

STATE BOARD OF PHARMACY No. 0031 AND BNDD No. PC0010152



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1848
February 19, 1975

Orig

E

ORIG NEW CORRES

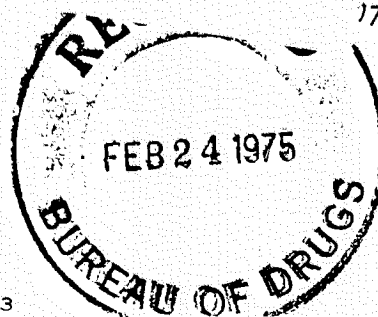
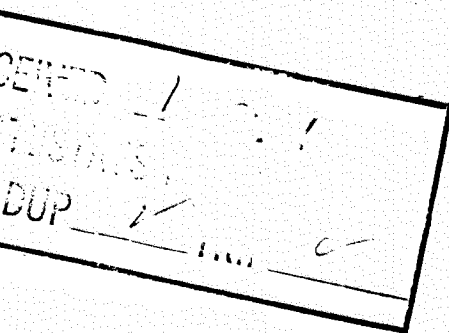
Food and Drug Adm.
Office of Scientific Evaluation
Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20852
Marvin Seife, M.D. - Director

Dear Dr. Seife,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
HCL 50 mg.

RE: Revision of issuing batch control numbers.

The revised batch control number will consist of five or six
digits, depending on the application.



175.

FEDERAL REGISTRATION NO. 18-10703
STATE BOARD OF PHARMACY NO. 003



CAMALL COMPANY

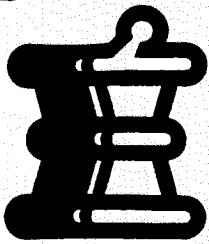
11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372 ~~xxxx~~ 0620

Sincerely,

A handwritten signature in cursive script, appearing to read "Eugene M. Schmall".

Eugene M. Schmall
CAMALL COMPANY

EMS/fmg



ORIG NEW CORRES

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1646

XXXX0620
January 17, 1975

Orig

Food and Drug Adm.
5600 Fishers Lane
Rockville, Md. 20852

Gentlemen,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

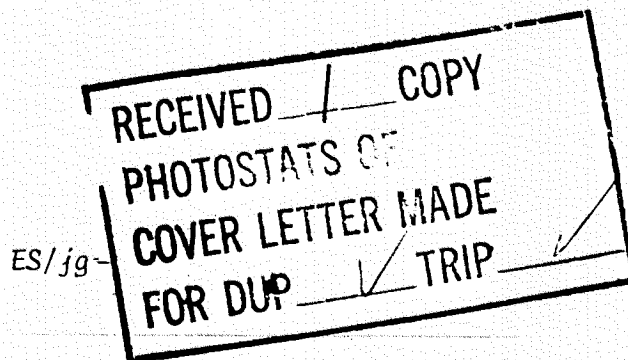
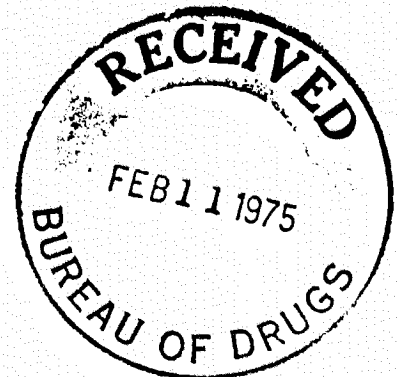
Re: Addition of Tablet Reconciliation sheet

See attached sheet.

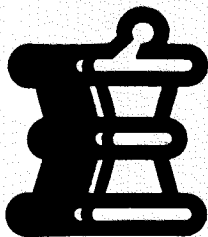
Sincerely,

Eugene M. Schmall

Eugene M. Schmall
CAMALL COMPANY



ES/jg-



NDA ORIG AMENDMENT

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-~~XXXX~~0620

January 13, 1975

Orig

Food and Drug Adm.
5600 Fishers Lane
Rockville, Md. 20852

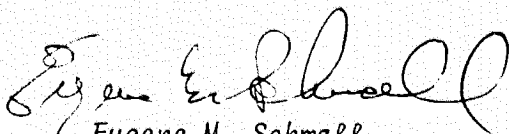
Gentlemen,

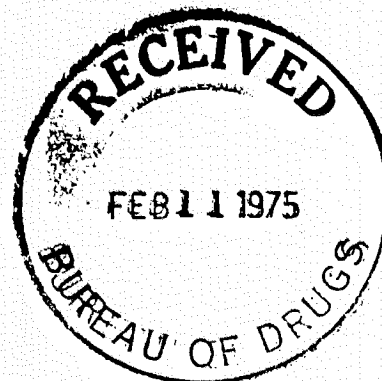
Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

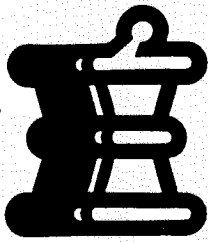
Re: Screen and blender numbers used in production.

See attached sheet.

Sincerely,


Eugene M. Schmall
CAMALL COMPANY





NDA ORIG AMENDMENT

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1946

January 13, 1975

Food and Drug Adm.
5600 Fishers Lane
Rockville, Md. 20852

Gentlemen,

Supplement Application ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

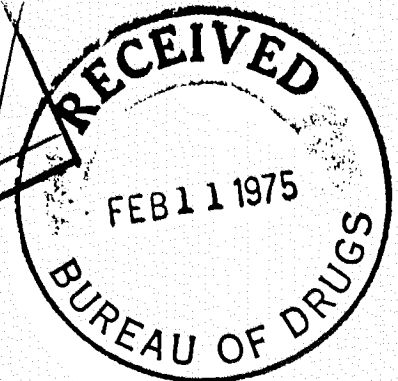
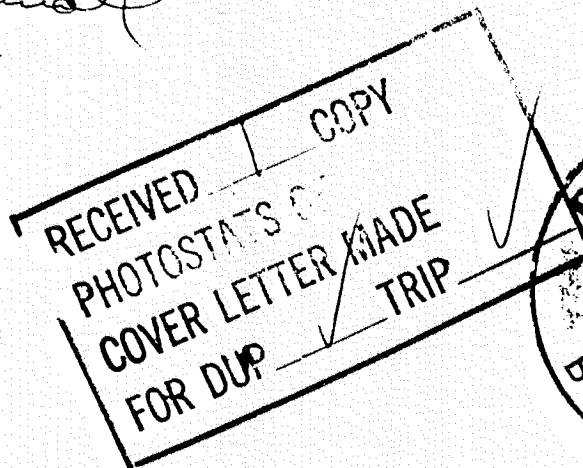
Re: Packaging master

See attached sheet

Sincerely,

Eugene M. Schmall
CAMALL COMPANY

ES/jg~



OCT 18 1976

NDA 83-965

Camall Company
Attention: Mr. Eugene Schmall
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

We acknowledge receipt of your communication (undated) received June 25, 1976, amending the application with (1) revised labeling and (2) updated manufacturing information.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. Copies of a printed package insert in accord with the submitted drafts.
2. Bioavailability data, in accord with your approved protocol.
3. Previously requested stability data.
4. A commitment to submit analytical results for the first five production batches manufactured.

Please let us have your response promptly.

Sincerely yours

/S/

MARVIN SEITE, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

176

NDA 83-965

AF _____

NOV 07 1975

Cannell Co.
Attention: Mr. Eugene Schwall
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

We acknowledge receipt of your communication dated September 29, 1975.

Reference is also made to our letters through May 23, 1975.

We have reviewed the material submitted and note that it is merely a re-copied version of your master formula sheet. We also note that (a) revised labeling (b) additional manufacturing information and (c) data to assure the bioavailability of the drug dosage form - requested in our letter of May 23, has not been submitted.

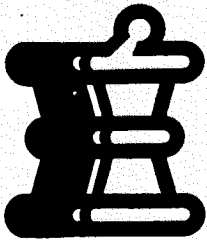
It is therefore requested that the above be submitted promptly.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

11/17/75



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-0620

NDA ORIG AMENDMENT

September 29, 1975

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Dear Sir:

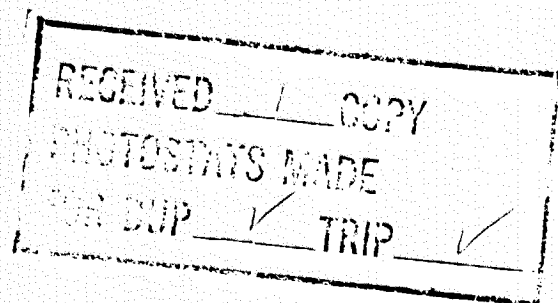
RE: Supplement to ANDA# 83-965

Please accept this as a supplement to ANDA# 83-965
Hydrochlorothiazide Tablets 50 mg.

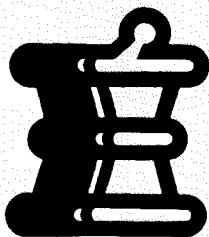
Thank you,

Eugene M. Schmall
Eugene M. Schmall

EMS/pjs



MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 6/10/75
FROM: <i>Chick</i>		OFFICE HFD-530
TO: <i>files</i>		DIVISION
SUBJECT: DMF		
SUMMARY Files for: approved & inspected in connection + The applicant for drug NAI for comment of 2/21/75		
SIGNATURE <i>/S/</i>		DOCUMENT NUMBER 83-965



CAMALL COMPANY 'ORIG NEW CORRES'

ORIG

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1000/0620

February 21, 1975

as per addend
Chul 6/10/75

Food and Drug Adm.
Office of Scientific Evaluation
Bureau of Drugs
5600 Fishers Lane
Rockville, Md. 20852
Marvin Seife, M.D.-Director

Dear Dr. Seife,

Supplemental Application to ANDA 83-965 Hydrochlorothiazide
Tablets 50 mg.

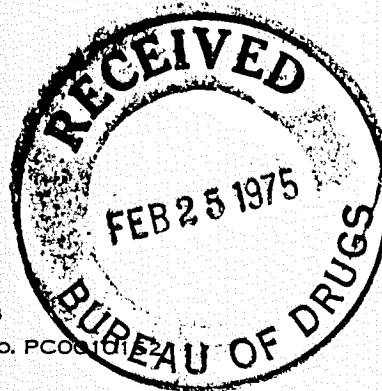
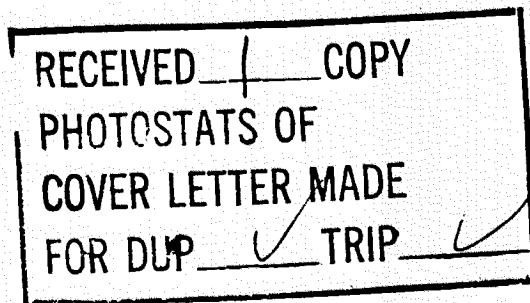
Re: Master File Number

Corp. (supplier of Hydrochlorothiazide
to Camall Co.) advises us that the Master File Number for the
Hydrochlorothiazide is

Sincerely,

Eugene M. Schmall
CAMALL COMPANY

EMS/jmg



NDA 83-965

MAY 23 1975

AF

Canall Co.
Attention: Mr. Eugene Schmall
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

We acknowledge receipt of your communications dated January 9, for distributors; and February 6, February 18, February 24 and March 31, 1975, containing manufacturing information.

The application provides for you to market the drug under your own label. It also provides for you to label the drug with a label showing distributors to be:

ries, Inc.

, Inc.

Canall Co.
NDA 83-965

-2-

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. For labeling:

a) Package insert: copies—in accord with labeling guidelines previously transmitted—should be submitted.

b) Container labels:

(1) Delete references to specific dosage amounts, replacing same with the phrase: "Usual Dose; See Package Insert."

a) Add or spell out the qualifying phrases, "Manufactured for..." or "Distributed by..."

b) Add the quantity of tablets per container.

c) Other: Include—after this application has been approved—distributor statements.

2. Include (a) copies of your analytical results for the new drug substance and the drug dosage form used in the bioavailability study and (b) a commitment to submit full analytical results for the first five production batches of the drug dosage form.

3. Include a full description of, and the data derived from studies of the stability of the drug; and a stability protocol that includes dissolution testing.

4. Submit samples of the drug dosage form.

5. Submit adequate data to assure the bioavailability of your drug dosage form—based upon your submitted protocol and our comments of October 7, 1974.

Please let us have your response promptly.

Sincerely yours,

/S/

Marvin Selfe, M.D.

Director

Division of Generic Drug Monographs

Office of Drug Monographs

Bureau of Drugs

11
1/23/75



NDA 83-965

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

OCT 07 1974

Camall Company
Attention: Mr. Eugene M. Schmall
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

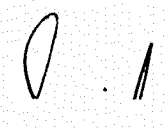
Reference is made to the protocol you submitted for bioavailability studies for Hydrochlorothiazide Tablets, 50 mg.

The protocol has been reviewed by our Division of Clinical Research and they have the following comments:

1. Each subject will be given a general physical examination including a medical history.
2. Each drug should be assayed for potency. In addition, dissolution studies should be conducted.
3. Tea and carbonated beverages are to be prohibited during the test days.
4. The amount of water intake prior to dosage for both test days should be the same.
5. The -1 to 0, 4-6, and 6-8 hour urine collection times which were omitted should be included.
6. The lot number's and the size of the production test batch should be remitted.
7. Each subject should be free of significant gastrointestinal, renal, and hepatic disease.
8. Each subject is to be informed that he is entirely free to withdraw from participation in the study at any time. Provision should be made for more than 20 volunteers to anticipate subject withdrawal.

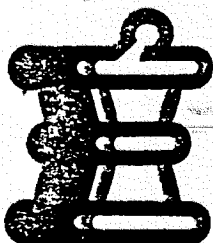
RECOMMENDATION:

The protocol is acceptable provided the above suggestions are incorporated into the study.

Sincerely yours, 

/S/
MARVIN SETTE, M.D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

SECTION THIRTEI



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-1948

PERSONALLY SUBMITTED BY

Joel Woods man
Reedley BAO
8-5-74

July 24, 1974

Department of Health, Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Md. 20852

Attention: Dr. M. Seife, M.D.

Re: NDA 83-965 for the drug Hydrochlorothiazide Tablets
50 mg., and your letter dated March 5, 1974

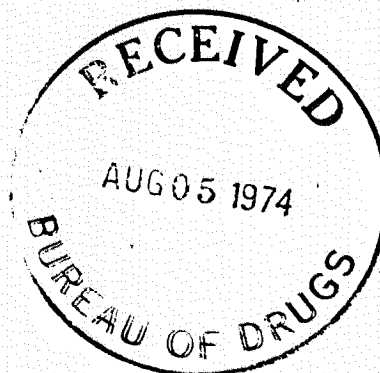
Dear Dr. Seife,

Camall Company is submitting this protocol for
the bioavailability study for Hydrochlorothiazide
Tablets 50 mg. NDA 83-965, according to your letter of
March 5, 1974.

Sincerely,

Eugene M. Schmall
Eugene M. Schmall
President, Camall Co.

EMS:aw



November 1, 1976

AMENDMENT

Eugene M. Schmall
11401 East 7 Mile Road
Detroit, Michigan 48234

ANDA 83-965

2/2/77
No reply
necessary
MS

Dear Mr. Schmall:

In answer to your letter which you received from Dr. Seife, on October 7, 1976, listing a number of comments pertaining to our protocol on the bioavailability of Hydrochlorothiazide Tablets which we submitted to you on August 24, 1976, we have the following comments:

1. That each subject will receive a general physical examination was covered in the first line of the experimental procedure.
2. The drugs have already been assayed for potency and the dissolution studies have been completed.
4. Is answered in the last paragraph on page 1, which says that eight (8 ounces) ounces of water will be given to each participant.
5. Is answered on the bottom of page 1, which states that urine collections would be taken before the test was begun and from 4 to 6 hours and 6 to 8 hours.
7. Is indicated under paragraph 1 of the experimental procedures which states that all subjects will be screened for a history of gastrointestinal, hepatic, renal and hemotological diseases or chronic alcohol consumption.
8. Is answered in number six of our outlined experimental procedure, as well as, in the second line of the first paragraph which states that sufficient subjects will be employed to have twenty-available for statistical analysis.

RECEIVED	COPY
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NOV 1 1976
DOCUMENT CONTROL SECTION

November 1, 1976

Since all the comments contained in the letter from Dr. Seife, were already present in the protocol, which I submitted to you, we will go ahead with plans to screen a sufficient number of subjects and begin the experiment as soon as possible.

Very truly yours,

S

ISI



11/18/76

FROM:

Marvin Seife, M.D.

OFFICE

TO:

Division of Biopharmaceutics

DIVISION

HFD-530

SUBJECT:

SUMMARY

Attention: Dr. Harold Murdock

NDA

83-965

Hydrochlorothiazide Tabs 50mg
Camell Company

Please review the bioavailability protocol on the above drug.

follow-up letter re protocol

Thank you,

/S/

Marvin Seife, M.D.

SIGNATURE

DOCUMENT NUMBER

Hydrochlorothiazide
50 mg Tablets
ANDA 83-965

Camall Company
Submission Dated:
November 1, 1976

REVIEW OF A SUBMISSION

This submission is a letter in response to Ms. Apone's review of the protocol submitted July 24, 1974. At that time was to do the study. However, since s replied to the questions raised in the review, it must be assumed they will do the study.

RECOMMENDATION:

The letter states that the laboratory has responded to the comments in the review and plan to begin the study right away. No recommendations are needed.

/S/

Harold R. Murdock, Ph.D.
Biopharmaceutics Review Branch



Rev 7F *ORIG*

CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-0620

RESUBMISSION
NDA ORIG AMENDMENT

Food & Drug Administration
Attn: Generic Drug Staff-HFD-530
5600 Fishers Lane
Rockville, MD. 20852

RE: NDA 83-965 FDA Letter October 18, 1976

Dear Dr. Seife,

Answers to your letter of October 18, 1976 RE: NDA 83-965
are as follows.

1) FDA Request - Copies of a printed package insert in accord with the
submitted draft.

Camall Answer - These have been ordered from the printer and when
available will be forwarded to you.

2) FDA Request - Bioavailability data, in accord with your approved
protocol.

Camall Answer - Bioavailability is in process and the results will
be submitted at the time we receive them.

3) FDA Request - Previously requested stability data.

Camall Answer - You will find stability data enclosed. (See inserts)

4) FDA Request - A commitment to submit analytical results for the first
five production batches manufactured.

Camall Answer - You will find commitments enclosed. (See inserts)



FEDERAL REGISTRATION NO. 18-10703

STATE BOARD OF PHARMACY NO. 0031 AND BNDD NO. PC0010152



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-0620

026

October 21, 1976

NDA ORIG AMENDMENT

Food and Drug Administration
Generic Drug Staff HKD- 530 Supplement
5600 Fishers Lane
Rockville, MD 20852

ATTN: Marvin Seife M.D.

RE: ANDA File # 83-965

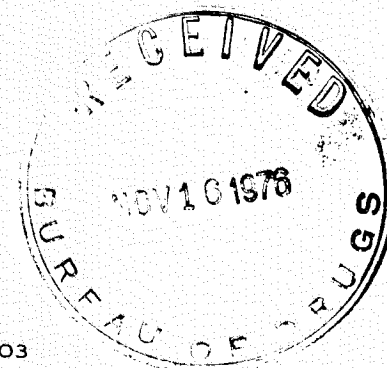
Dear Dr. Seife,

Please amend our ANDA File # 83-965 by deleting pages B, G, & M of Section 11, and replacing with the enclosed pages, B, G, M, of Section 11. Thank you.

Sincerely yours,

Eugene M. Schmall, President
Camall Company

EMS/cw



FEDERAL REGISTRATION NO. 18-10703

STATE BOARD OF PHARMACY NO. 0031 AND BNDD NO. PC0010152



CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-0620

October 28, 1976

NDA ORIG AMENDMENT

Generic Monograph Drug Staff HFD-530
5600 Fishers Lane
Rockville, MD 20852

Attn: Dr. Marvin Seife M.D.
RE: ANDA 83-965 Supplement to:

Dear Dr. Seife:

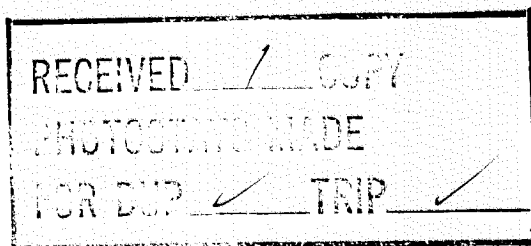
Please accept the following documents as part of our ANDA File
#83-965 Hydrochlorothiazide 50 mg tablet.

Thank you

Sincerely yours,

Eugene M. Schmall/mg
Eugene M. Schmall, President
Camall Company

EMS/mg



FEDERAL REGISTRATION NO. 18-10703

STATE BOARD OF PHARMACY NO. 0031 AND BNDD NO. PC0010152

FEB 10 1977

MDA 83-965

Camall Company
Attention: Mr. Eugene Schmitt
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets.

We acknowledge receipt of your communications dated October 21, and 28, 1976; and undated (received November 16, 1976), amending the application.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. Printed labeling in accord with your commitments.
2. Additional stability data; here, dissolution should be performed at each testing station.
3. Analytical results, in accord with your commitment, after approval of this application.
4. Bioavailability data - when available.

Please let us have your response promptly.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

J Meyer 2/1/77

1/1/77

MAR 09 1977

NDA 83-965

Camall Company
Attention: Mr. Eugene M. Schmall
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets.

We acknowledge receipt of your communication dated February 15, 1977, amending the application, with (1) copies of printed labeling (2) additional control information and (3) a commitment to submit bioavailability data.

We have reviewed the material submitted and request submission of the bioavailability data---when available.

The material submitted is being retained in our files.

Sincerely yours.

/S/

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

9/77

copy - 5/77

February 8, 1977

SUBMITTED TO: Camall Company
Detroit, Michigan

ASSAY NUMBER: 71292

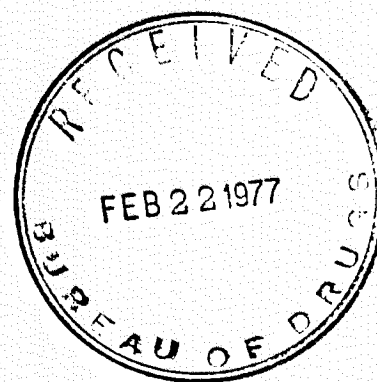
DATE RECEIVED: November 23, 1976

TEST MATERIAL: 1 x 100 Hydrochlorothiazide 50 mg.
Camall Control # 5-2776

1 x 100 Merck Hydrodiuril 50 mg.
Lot # T 3706

SUBJECT OF ASSAY:

To compare the urine excretion levels in humans, produced by the submitted test materials, initially and in a cross-over study.





CAMALL COMPANY

11401 EAST 7 MILE ROAD • DETROIT, MICHIGAN 48234 • 372-0620

February 21, 1977

ORIG NEW CORRES

Food and Drug Administration
Department of Health, Education and Welfare
5600 Fishers Lane
Rockville, MD 20852

ATTN: Marvin Seife M.D.
RE: ANDA #83-965 Hydrochlorothiazide Tablets

Dear Dr. Seife,

In response to your letter of February 10, 1977,
concerning Hydrochlorothiazide Tablets, please find the
enclosed completed bioavailability data.

Thank you.

Sincerely yours,

Eugene M. Schmall, President
Camall Company

EMS/mg

Enc.

NDA 83-965

MAR 21 1977

Camall Company
Attention: Mr. Eugene M. Schmall
11401 East 7 Mile Road
Detroit, MI 48234

Gentlemen:

Reference is made to your abbreviated new drug application for Hydrochlorothiazide Tablets, 50 mg.

The accompanying approval does NOT provide for distributors. If you so elect, you should submit a separate supplement for each proposed distributor and an accompanying distributor's statement, as follows:

Include a signed statement from the proposed distributor to show that he is regularly and lawfully engaged in the distribution or dispensing of prescription drugs; the category of his operation (repackager, relabeler, wholesaler, retail pharmacy, etc.) and that he agrees to distribute the drug only under the labeling provided for in the application and that no changes will be made in the labeling unless such changes are provided for in a supplement to this application.

Sincerely,
/S/

Marion Seife, M.D.

Director

Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

12/77